Doctor's Note — Clinical Trial Summary

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TRIAL

A First-In Human (FIH) Study to Find Out How Well REGN10597 Medicine Given Alone or in Combination With Cemiplimab Works in Adult Participants Who Have Cancer With Tumors That Have Spread in Their Body

NCT ID: NCT06413680 Phase: PHASE1 / PHASE2 Sponsor: Regeneron Pharmaceuticals Status: Recruiting

SUMMARY

This study is researching an experimental drug called REGN10597 alone or in combination with another drug called cemiplimab (called "study drug(s)"). The study is focused on patients with certain solid tumors that are in an advanced stage.

The aim of the study is to see how safe, tolerable, and effective the study drug(s) are.

The study is looking at several other research questions, including:

* What side effects may happen from taking the study drug(s)
* How much study drug(s) is in the blood at different times
* Whether the body makes antibodies against the study drug(s) (which could make the study drug(s) less effective or could lead to side effects)

KEY ELIGIBILITY CRITERIA

- Dose escalation cohorts:
- 1\. Histologically or cytologically confirmed diagnosis of solid malignancy (locally advanced or metastatic) with confirmed progression on standard-of-care therapy. Participants are required to submit archival tissue if it is available
- Dose expansion cohorts:
- 1\. Histologically of cytologically confirmed diagnosis of one of the following tumors with criteria, as defined in the protocol:
- * Module 1, Cohort 1: anti-PD-(L)1 Progressed Melanoma or
- * Module 1, Cohort 2: anti-PD-(L)1 Progressed RCC or
- * Module 2, Cohort 1: 1L Melanoma ALL Participants ARE REQUIRED to submit fresh pretreatment biopsy during screening, with an additional exploratory biopsy at other time points
- 1. Prior treatment with Interleukin 2 (IL2)/IL15/IL-7 given outside the context of concurrent administration with adoptive cell therapy
- 2. Prior treatment with anti-PD1/PD-L1, or an approved systemic therapy or any previous systemic non-immunomodulatory biologic therapy within 4 weeks, as defined in the protocol
- 3. Has received radiation therapy or major surgery within 14 days prior to first dose of study drug or has not yet recovered from AEs

Total sites: 11 | 11 currently recruiting

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